CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

NEW ACCOUNT APPROVAL

1.0 PURPOSE

The Federal Controlled Substances Act requires pharmaceutical wholesalers to maintain effective controls to guard against the diversion of controlled substances. This Standard Operating Procedure (SOP) outlines the review of potential customers prior to the distribution of controlled substance products.

2.0 SCOPE

This SOP applies to Retail Independent, Long Term Care, Practitioners, and Hospital customers within the following businesses: Pharmaceutical Distribution, except as otherwise provided in procedures specific to the business unit.

Retail Chain, National Mail Order, National Alternate Care, National Long Term Care, or any other National account pharmacies bound by a Prime Vendor Agreement (PVA), who are corporately owned and operated and whose corporate entitiy makes all decisions regarding purchasing, compliance, policies and procedures, on behalf of all satellite facilities where there is no independent ownership or decision making outside of the corporate entitiy, are excluded from this SOP.

3.0 REFERENCES / RELATED DOCUMENTS

[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C010.docx"]{- ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C010.docx" }~~	Document Management in Content Manager
[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C012.docx"]{- ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C012.docx" }~~	Closed Door Pharmacy Customers

DEFENDANT EXHIBIT
CAH-WV-00103

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[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C013.docx"]{- ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C013.docx"~~ }	Closure of Customer Accounts
[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C015.docx"]{- ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C015.docx"~~ }	Secondary Market Account Set-Up
[HYPERLINK "http://www.cardinalhealth.com/ltcinfusionsurvey" \o "http://www.cardinalhealth.com/ltcinfusionsurvey"]{- ~~HYPERLINK "http://www.cardinalhealth.com/ltcinfusionsurvey" \o "http://www.cardinalhealth.com/ltcinfusionsurvey"~~ }	Long-term Care and Infusion Services Questionnaire

[HYPERLINK "http://www.cardinalhealth.com/RIsurvey" \o "http://www.cardinalhealth.com/RIsurvey"]{- HYPERLINK "http://www.cardinalhealth.com/RIsurvey" \o "http://www.cardinalhealth.com/RIsurvey" }	Retail Independent Pharmacy Questionnaire
[HYPERLINK "http://www.cardinalhealth.com/us/en/ACSurvey/"]{- HYPERLINK "http://www.cardinalhealth.com/us/en/ACSurvey/" }	Ambulatory Care Questionnaire
[HYPERLINK "http://www.cardinalhealth.com/us/en/HospitalSurvey/"]{ HYPERLINK "http://www.cardinalhealth.com/us/en/HospitalSurvey/" }	Hospital and Surgery Center Questionnaire
[HYPERLINK "mailto:GMB-DUB-QRA-Secondary%20Market@CardinalHealth.com"]{- HYPERLINK "mailto:GMB-DUB-QRA-Secondary%20Market@CardinalHealth.com" }	Corporate QRA Secondary Market Group Mailbox

\\cardinalhealth.net\group\OH001\CORP\Quality\QRA\Compliance\Compliance\Anti-Diversion Initiative\Anti-Diversion Team folder\Reference Documents\New Accounts	Anti-Diversion New Customer Set-up Checklist (061 - New Account Checklist)

4.0 RESPONSIBILITIES

The Cardinal Health Pharmaceutical Distribution sales teams have the responsibility of collecting all of the required documents for account set-up, prior to submitting a request to onboard a new customer.

The QRA Account Setup team has responsibility for making decisions to guard against the diversion of controlled substances and to determine if customers represent an acceptable business risk to Cardinal Health.

5.0 DEFINITIONS

Alprazolam, Hydrocodone, Oxycodone and Phentermine (AHOP)	A list of products that are monitored by Cardinal Health on a regular basis because they are drugs considered high risk for potential diversion.
Anti-Diversion Centralization *(ADC) Chrome*	Cardinal Health system that manages held orders data and allows users to restrict Drug Enforcement Agency numbers from purchasing controlled substance products. This tool is linked to the Central Customer Database (CCDB) application and CCDB DEA Compliance tool.
Anti-Diversion New Customer Set-up Checklist	Document used to create the complete Drug Enforcement Agency due diligence packet for the new customer review. Using the approved naming convention this document is categorized as 061 in Content Manager.
Central Customer Database (CCDB)	Cardinal Health system that stores customer data.
Central Customer Database (CCDB) DEA Compliance Tool	Application used to restrict Drug Enforcement Agency numbers from purchasing controlled substance products. This tool is linked to CCDB application.

Closed Door Pharmacy	Any pharmacy other than a retail pharmacy, and any pharmacy that is limited by contract or otherwise from reselling, in the retail market prescription pharmaceuticals it has purchased from Cardinal Health. Closed door pharmacies include a pharmacy that purchases pharmaceuticals under a Manufacturer's contract in order to service non-retail customers such as nursing homes, hospitals, home care, or long-term care facilities.
Content Manager	IBM system used by Corporate Quality and Regulatory Affairs as a data repository.

Diversion	Diversion is defined in multiple ways:
	• Product diversion
	  ○ Excessive purchases of controlled substances with intent to sell or use illicitly
	  ○ Introduction into the market of pharmaceuticals that are counterfeit, adulterated, misbranded, improperly store or shipped, or otherwise unreliable.
	  ○ Improper sales into the secondary market.
	  ○ Improper internet sales
	  ○ Theft
	• Price diversion
	  ○ Any use or sale of a pharmaceutical product by a closed-door or retail pharmacy that violates "own use"

Know Your Customer (KYC) Questionnaire	Survey used to collect information about Cardinal Health customers. The survey contains, among other items, questions specific to the customer's business model and controlled substance needs.
Manufacturer	An establishment that is authorized to engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs, as reflected in a registration with the United States Food and Drug Administration (FDA) or an establishment that submits listing information directly to the FDA and has been assigned a Labeler Code.
Practitioner	Any Drug Enforcement Agency registrant assigned a corresponding Business Activity Code of C (Practitioner).
Wholesaler	An entity that engages in the business of distributing prescription drugs to persons other than those with prescriptions or their agents, but does not include Manufacturers or Final Dispensers.

6.0 PROCEDURE

6.1 General Information

6.1.1 Prior to the initial sale of controlled substance products, the QRA Account Setup team conducts a thorough review of the proposed customer. If the customer, at the conclusion of the process, is determined to pose an unreasonable risk for diversion, controlled substance products are not sold to the customer.

6.2 Sales/Customer

6.2.1 The Sales teams instruct customers to complete the appropriate KYC Questionnaire

a. Retail Independent: [HYPERLINK "https://cardinalhealth.us2.qualtrics.com/SE/?SID=SV_3IgzwFFt5K9EzSl"]{ HYPERLINK "https://cardinalhealth.us2.qualtrics.com/SE/?SID=SV_3IgzwFFt5K9EzSl" }
b. Long Term Care/Home Infusion: [HYPERLINK "https://cardinalhealth.us2.qualtrics.com/SE/?SID=SV_1LYudupqyVevSoB"]{ HYPERLINK "https://cardinalhealth.us2.qualtrics.com/SE/?SID=SV_1LYudupqyVevSoB" }
c. Hospital/Surgery Center: [HYPERLINK "https://cardinalhealth.us2.qualtrics.com/SE/?SID=SV_81XK0BkwDzUhZ3f"]{ HYPERLINK "https://cardinalhealth.us2.qualtrics.com/SE/?SID=SV_81XK0BkwDzUhZ3f" }
d. Ambulatory Care Facility: [HYPERLINK "https://cardinalhealth.us2.qualtrics.com/SE/?SID=SV_7Qy6MYlsKiFckGF"]{ HYPERLINK "https://cardinalhealth.us2.qualtrics.com/SE/?SID=SV_7Qy6MYlsKiFckGF" }
e. Ambulatory Care Practitioner: [HYPERLINK "https://cardinalhealth.us2.qualtrics.com/SE/?SID=SV_ehUvwbEt9BOy7s1"]{ HYPERLINK "https://cardinalhealth.us2.qualtrics.com/SE/?SID=SV_ehUvwbEt9BOy7s1" }

6.2.2 Once completed, the KYC Questionnaire is systematically routed to GMB-DUB-KYC-Surveys, where it is attached to the appropriate NAS SharePoint request by the sales support team.

6.3 Recording of KYC

6.3.1 The QRA Account Setup Team save KYC Questionnaires in Content Manager using the approved naming convention as defined in SOP [HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C010.docx"]{ ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C010.docx" }.

6.4 QRA Due Diligence Process: Analysis of Information

6.4.1 Requests are received via NAS SharePoint (Pharmaceutical Distribution).

6.4.2 A review of the SharePoint request is conducted to verify that all of the needed documentation is attached which may include but is not limited to:

a. Customer DEA license #
b. KYC questionnaire
c. Dispense data – When needed for a Florida retail customer or Florida Practitioner.
d. Customer state license #'s

6.4.3 The QRA Account Setup team validates that the request has not been previously denied from purchasing controlled substances from Cardinal Health. This information is verified by accessing the CCDB DEA Compliance Tool and reviewing whether the customer DEA# has been blocked or not, as well as determining if a block exists in ADC for the account.

6.4.4 The QRA Account Setup team reviews the information provided by the customer in the KYC questionnaire which includes but is not limited to:

a. General information such as address, city, state, zip, and web site
b. State and Federal Licensure is verified and reviewed for disciplinary actions related to controlled substances.
c. Business Model Information.
d. Ownership information.
e. Pharmaceutical product volume, specifically with regards to certain controlled substances.
f. Filling new prescriptions via the internet.
g. Filling prescriptions for out-of-state patients and/or prescribers.

h. Warranty, Compliance, and Ryan Haight Act Agreements

6.4.5 If the proposed new customer is a retail independent account, or Practitioner and resides within the state of Florida, then the following additional steps must be completed:

6.4.5.1 Determine clinical nature of the receiving entity.

6.4.5.2 Review customer's history of Schedule II and Schedule III controlled substance purchases.

6.4.5.3 Determine if customer's Schedule II and Schedule III controlled substance purchasing history, if any, is consistent with and reasonable for that entity's clinical business needs.

6.4.6 If during the review process, the customer is identified as a closed door pharmacy ([HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C012.docx"]{ ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C012.docx" }) or Wholesaler/Distributor ([HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C015.docx"]{ ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C015.docx" }5) a notification needs to be sent to the Corporate QRA-Secondary Market Group Mailbox for further review.

6.5 Additional Review & Decision Making

6.5.1 The QRA Account Setup team will review each request based on the business unit or accounting class type, and the correspsonding KYC questionnaire that pertains to that business unit or accounting class type. Information will be reviewed and documented within the Account Setup Checklist – 061, based on the business unit or accounting class type and the corresponding KYC questionnaire for that business unit or accounting class type.

6.5.1.1 If red-flags are identified, the QRA Account Setup Specialist may request additional supporting information related to the identified red-flag from the Sales team. Upon receipt of the requested follow-up information from Sales, the QRA Account Setup Specialist determines whether the response is reasonable given the set of available known facts related to the identified red-flag.

6.5.1.1.1 If needed, the QRA Account Setup Specialist can engage the QRA Pharmacist team by providing them an email outlining the potential red flags identified along

with any other relevant supporting documentation. The QRA Pharmacist team can then review the account packet, and make a decision to approve or reject the account, based on whether or not the customer appears to pose an unreasonable risk for the diversion of controlled substances.

6.5.1.2 If any of the scenarios below are identified during the review of the proposed new customer, then the QRA Pharmacist team can be engaged to aid in the review of the account prior to finalizing a decision regarding the account.

a. Disciplinary actions or findings that specifically reference the dispensing, abuse, and/or record keeping of controlled substances. The disciplinary action could be for any person associated with this account (Pharmacist in Charge (PIC), Owner, Physician, Pharmacist, Pharmacy Technician, etc.) and also includes those disciplinary actions that are pending final decision.
b. Multiple red flags, as outlined in the Anti-Diversion New Customer Set-up Checklist.
c. When requested follow-up information received from Sales or from the customer does not appear to be reasonable or correspond to the customer's business model.
d. Dispensing numbers are higher than current (appropriate) baseline threshold limits for the corresponding customer segment and/or dispense data received does not support the quantities stated in the KYC Questionnaire.
e. The review of the account creates questions that warrant additional review.

6.5.2 Final decision to approve or reject the account is based on whether the customer appears to pose an unreasonable risk for the diversion of controlled substances or not.

6.5.3 If rejected, the QRA Account Setup Specialist blocks the potential customer's DEA number using ADC and provides relevant information in the comment section within ADC and the SharePoint request ([HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C013.docx"]{~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C013.docx" }).

6.6 Recording of Decision

6.6.1 The QRA Account Setup Specialist compiles all documents used and referenced during the assessment, notates relevant comments in the New Customer Setup Checklist – 061, and documents the final decision in the New Customer Set-up

Checklist - 061. This document is retained in Content Manager.

6.6.1.1 The electronic template of the Anti-Diversion New Customer Set-up Checklist is titled "061 - New Account Checklist.pdf" and it can be found on the QRA Network drive under the "New Accounts" folder.

6.7 Communication of Decision

6.7.1 For requests received through the NAS SharePoint site, the QRA Account Setup Specialist finalizes the decision by selecting the appropriate radio button to complete the request.

7.0 DOCUMENTATION REQUIREMENTS

7.1 Documentation Guide(s) and Practices

7.1.1 Account setup requests must have the following documents stored in Content Manager:

a. KYC Questionnaire
b. Anti-Diversion New Customer Set-up Checklist

7.2 Documentation Retention

7.2.1 All documentation required within this SOP must be maintained for three (3) years in Content Manager.

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Approvals					
Approvals on file in the Pharmaceutical Distribution Corporate Document Center Approvers: Julie Kuhn				Owner: Patrick Dudley PDCDC Coordinator: Jason Paul Snouffer	
Change History					
DCN	Effective Date	Change Type	Training Required	Document Applicability	Training Assignment(s)
3075	18 Jul 2013	Scheduled Review	Yes	Corporate	PDQRA - Analytics and SOM Compliance PDQRA - Pedigree PDQRA - Secondary Market PDQRA - SOM Independent Sales
Other (specify)					
N/A					
Change Description and Justification					
Scheduled review. Updated to comply with current Cardinal Health policies and practices.					